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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,351	11/26/2003	Wayne D. Comper	62386-043	6164

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,351	COMPER, WAYNE D.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/26/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment filed November 26, 2003 is acknowledged. Claims 22-32 are pending and under examination. The numbering of claims is not in accordance with 37 CFR 1.126 because there are two claims that are labeled "claim 28". Misnumbered claims 28-31 been renumbered as 29-32.

Specification

2. The specification is objected to for failing to update the status of the related applications to which the instant application claims priority. Correction is required.

Claim Objections

3. Claims 28 and 29 are objected to for the following minor informalities:

- Claim 28 contains incomplete parentheses pair at the words "nephrolithiasis", "gout" and "cardiovascular disease", for example. Applicant should correct any other improper punctuation throughout claim 28.
- Claim 28, "medullary sponge" and "preeclampsia" are misspelled.
- Claim 29 should start on a new line rather than after the period of claim 28.
- Claim 29 improperly depends from cancelled claim 1. For purposes of compact prosecution, claim 29 will be interpreted as dependent from claim 22.
- The acronyms "GU" and "COPD" in claim 27 should be spelled out at their first recitation.
- Claim 28 contains duplicate diseases, such as diabetes insipidus.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how some of the "diseases" listed in claim 28 qualify as diseases. For example, preeclampsia, trauma, surgery, extensive injury, burns, induction of anesthesia, drug abuse and side effects of use of drugs are not diseases. Further, "extensive" injury and drug "abuse" are relative terms for which the metes and bounds of injury and drug use cannot be determined. Many of the diseases and conditions listed in claim 28 are syndromes/anonamlies that must be diagnosed with multiple symptoms, not just a urine profile. It is unclear how Applicant intends to identify syndromes with a single symptom of urine analysis. Correction is required to overcome this rejection.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method of diagnosing a variety of diseases comprising

generating a fragmentation profile for at least one protein from a urine sample obtained from a subject, and comparing said fragmentation profile with a reference fragmentation profile for said at least one protein of a normal individual to determine the presence of disease(s). The specification does not put one of skill in possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the specification only provides partial structure of the proteins (of the fragmentation profile) used to detect the genus of diseases and associated proteins (listed in claims 28 and 31). There is not even identification of any particular portion of the protein structure that must be conserved. The fragmentation profiles (fragment size and sequence) of the various diseases have not been determined in sick or healthy individuals, nor has the specification shown possession of a method of determine the fragmentation profiles. The diseases included in the method are:

Nephropathy
Diabetes insipidus
Diabetes type I
Diabetes type II
Renal disease
Glomerulonephritis
Bacterial glomerulonephritis
Viral glomerulonephritis
IgA nephropathy
Henoch-Schölein Purpura
Membranoproliferative glomerulonephritis
Membranous nephropathy
Sjögren's syndrome
Nephrotic syndrome
Minimal change disease
Focal glomerulosclerosi
Acute renal failure
Acute tumulointerstitial nephritis
Pyelonephritis
GU tract inflammatory disease
Preeclampsia
Renal graft rejection
Leprosy
Reflux nephropathy
Nephrolithiasis
Genetic renal disease
Medullary cystic

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Medullary sponge
Polycystic kidney disease
Autosomal dominant polycystic kidney disease
Autosomal recessive plycystic kidney disease
Tuberous sclerosis
Von Hippel-Lindau disease
Familial thin-glomerular basement membrane disease
Collagen III
Glomerulopathy
Fibronectin glomerulopathy
Alport's syndrome
Fabry's disease
Nail-Patella Syndrome
Congenital urologic anomalies
Monoclonal gammopathies
Multiple myeloma
Amyloidosis
Febrile illness
Familial Mediterranean fever
HIV infection- AIDS
Inflammatory disease
Systemic vasculitides
Polyarteritis nodela
Wegener's granulomatosis
Polyarteritis
Necrotizing
Crescentic glomerulonephritis
Polymyositis-dermatomyositis
Pancreatitis
Rheumatoid arthritis
Systemic lupus erythematosus
Gout
Blood disorders
Sickle cell disease
Thrombotic thrombocytopenia purpura
Hemolytic-uremic syndrome
Acute cortical necrosis
Renal thromboembolism
Trauma
Surgery
Extensive injury
Burns
Abdominal and vascular surgery
Induction of anesthesia
Side effect of use of drugs
Drug abuse
Malignant disease
Adenovarcinoma
Melanoma
Lymphoreticular
Multiple myeloma
Circulatory disease
Myocardial infarction
Cardiac failure
Peripheral vascular disease
Atherosclerotic cardiovascular disease
Skin disease
Psoriasis
Systemic sclerosis
Respiratory disease
COPD
Obstructive sleep apnoea
Hypoia at high altitude
Endocrine disease
Acromegaly
Diabetes mellitus

The specification clearly does not demonstrate possession of fragmentation profiles that diagnose these diseases. One would have to discover and construct profiles for each disease based on age, race, sex, and a number of other factors to determine fragmentation profiles for

various individuals. Applicant has not done this work and therefore does not possess the fragmentation profiles that diagnose these diseases in all individuals. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived.

6. Claims 22-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As outlined above, the claims are drawn to a method of diagnosing a variety of diseases comprising generating a

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fragmentation profile for at least one protein from a urine sample obtained from a subject, and comparing said fragmentation profile with a reference fragmentation profile for said at least one protein of a normal individual to determine the presence of disease(s). The specification does not enable one of skill to practice the claimed invention. There is no guidance for determining the fragmentation profiles of the various diseases in various individuals/groups. There are no working examples of constructing a fragmentation profile for gout, burns, trauma, surgery, etc. The specification fails to teach what kind of proteins and fragments are indicative of what disease(s). Without this knowledge, one of skill cannot diagnose diseases. The specification clearly does not demonstrate enablement of diagnosis because one would have to discover and construct profiles for each disease based on age, race, sex, and a number of other factors to determine fragmentation profiles for various individuals. Applicant has not done this work and therefore has not enabled one of skill to diagnose diseases with the yet-to-be-discovered fragmentation profiles. Therefore, the specification does not enable the practice of the claimed invention for any disease because fragmentation profiles of the "normal" versus "sick" have not been constructed and the specification does not teach how to make the fragmentation profiles that diagnose the diseases listed in claim 28.

Conclusion

7. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
August 2, 2005